



ALABAMA STATE BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

Alabama Rule Changes Effective January 14, 2024

Collaborative Practice

The Alabama State Board of Pharmacy and the Alabama Board of Medical Examiners amended Rule 680-X-2-.44 Collaborative Practice to empower pharmacists to test and treat patients with an “acute, uncomplicated illness or injury,” including influenza and streptococcus. The protocol for test to treat influenza and streptococcus was approved by the Board of Pharmacy and the Board of Medical Examiners at their respective December board meetings.

A copy of the updated rule and protocol is available on the Board website at www.albop.com. Application information is also available on the Board website.

Emergency Prescription Refills

The Board of Pharmacy and the Board of Medical Examiners amended Rule 680-X-2-.26 to expand authorization of pharmacist dispensing of emergency refills.

(1) If a pharmacist receives a request for a prescription refill, and the pharmacist is unable to readily obtain refill authorization from the prescriber, the pharmacist may dispense a **one-time** emergency refill of up to a 72-hour supply of the prescribed medication or the smallest dispensable package size if a 72 hour supply is not readily available, under the following conditions:

(a) The prescription is not a medicinal agent listed in Schedule I or II pursuant to Title 20,

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Chapter 2, or the controlled substance list for Schedule I or II maintained by the State Board of Health.

(b) The medication is essential to the maintenance of life or the continuation of therapy and in the pharmacist's professional judgement, the interruption of therapy might reasonably produce undesirable health consequences or may cause physical or mental discomfort.

(c) The pharmacist has a record of a prescription at the pharmacy or has been presented proof of a prescription filled within the last 90 days in the name of the patient for whom the request of the emergency supply is being made.

(d) A pharmacist or pharmacy shall not dispense or sell the same drug to the same patient, as provided in this section, more than one time in any 12-month period.

(e) The pharmacist must inform the patient or the patient's representative at the time of dispensing that the refill is being provided without the practitioner's authorization, and that practitioner authorization is required for any future refill.

(f) The dispensing pharmacist shall create a written prescription order containing all of the prescription information required by federal and state statutes, rules and regulations and shall also include the statement "Emergency Fill."

(g) The dispensing pharmacist shall notify the prescriber orally or in writing of the emergency dispensing within twenty-four (24) hours after such dispensing.

Drug Manufacturers; Wholesale Distributors; Private Label Distributors, Repackagers, Third-Party Logistics Providers, Outsourcing Facilities; Reverse Distributors; Retail Medical Oxygen Suppliers

The Board amended 680-X-2-.23 to address the additional requirement for registering designated representatives and added application and renewal requirements, which allowed for the repeal of 680-X-2-.25.

(a) The Alabama State Board of Pharmacy shall require that manufacturers, wholesale drug distributors, private label distributors, repackagers, and third-party logistics providers have a designated representative who has appropriate education and/or experience to assume responsibility for positions related to compliance with state licensing requirements.

1. All designated representatives shall register with the Alabama State Board of Pharmacy. The initial registration fee and renewal fee shall be one

hundred dollars (\$100). All designated representatives shall pay the renewal fee annually with this fee being due on October 31 and delinquent after December 31 annually. All designated representative registrations shall expire on December 31 annually. If the renewal is not timely received by the board, the applicant shall pay a penalty of fifty dollars (\$50) for each month the renewal is late.

2. The designated representative shall:

- i. Be at least 21 years of age.
- ii. Be a citizen of the United States or, if not a citizen of the United States, a person who is legally present in the United States with appropriate documentation for the federal government.
- iii. Be employed by the facility full-time in a position of authority and be physically present at the facility for a minimum of 50% of the hours the facility is in operation or at least thirty (30) hours per week, whichever is less.
- iv. Be actively involved in and aware of the actual daily operation of the facility.
- v. Serve as a designated representative for only one physical location for a permitted facility at any one time.
- vi. Not have been convicted of a violation of any federal, state, or local law relating to any drug offense.
- vii. Not have been convicted, received adjudication, community supervision, or deferred prosecution of any felony offense or any crime related to fraud, violence, sexual violations or related to the practice of pharmacy.

3. If the permit holder's designated representative will be or is no longer employed or no longer desires to act as a designated representative, the permit holder shall notify the Board within ten (10) days of the change in designated representative by completing the "Notice of Change of Designated Representative" form provided by the Board.

4. If the permit holder is unable to maintain a designated representative, the permit holder shall notify the Board within ten (10) days with an action plan to designate another designated representative. This plan shall not exceed ninety (90) days before the permit holder is in violation of operating a facility without a designated representative, at which time the Board may require closure of the facility until a designated representative assumes his/her duties.

5. In addition to all other applicable requirements for registration as a designated representative and a prerequisite for consideration of registration as a designated representative, each individual seeking registration shall consent and be subject to a Board approved criminal background check, the cost of which to be paid by the applicant. The information received as a result of the background check shall be relied upon in determining whether the applicant meets the applicable qualifications to obtain the referenced registration.

(b) The Alabama State Board of Pharmacy shall require that outsourcing facilities have an Alabama licensed supervising pharmacist for the individual location and comply with 680-X-2-12.

A Special Thank You to Our Volunteers

Thank you to all the pharmacists who have attended work group and focus group meetings over the past several months. These meetings have been valuable in obtaining feedback from practitioners related to many areas of regulatory compliance. The Board will continue to coordinate these meetings, and licensees should know that the continued communication will aid Board members as they review and address rules and regulations going forward.

2023 Milestones

Celebrating 50 Years of Pharmacy Licensure

- Vance Alexander
- Ricky Bearden
- Jerry Bonner
- Richard Bowie
- Roger Burnett
- Virginia Chambers
- Ralph Christopher
- William Crew
- Danny Guest
- Thomas Henderson
- Kerry Kelley
- Donald Kyle
- James Marbut
- William McGuffey
- Anita Pritchett
- Wendell Qualls
- Raymond Robertson
- Richard Ryan
- Linda Sellers
- Clifton Shaw
- Gary Sheffield
- Robert Slay

- Audrey Spangler
- Charles Synco
- George Thompson
- Joseph Vacca
- George Wheeler
- Daniel Williamson
- Grover Young

Celebrating 60 Years of Pharmacy Licensure

- William Beasley
- James Jackson
- Bobby Maise
- George Payne
- Roy Sanderson
- Mark Shelley

Celebrating 65 Years of Pharmacy Licensure

- Clinton Hardy
- John Cleveland
- Anthony Brooklere

Thank You!

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